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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,208	CONNER ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *3-9 and 14-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 1-2 and 10-13, drawn to an isolated nucleic acid comprising a sequence, wherein said isolated nucleic acid is a promoter, classified in class 536, subclass 24. 1, for example, and SEQ ID NO: 90, in the reply filed on February 13, 2006 is acknowledged.

The traversal is on the ground(s) that the complete examination of the application would be handled most expeditiously by treating all of the pending claims as a single entity, as a search and examination of the entire application would not cause a serious burden. Applicants submit that restriction to a single nucleotide sequence is improper, and furthermore submit that no serious burden would result by the search and examination of all disclosed nucleotide sequences, as all sequences are members of the same class of gene regulatory elements, specifically, elements regulating male reproductive tissue genes identified from *Zea mays* (reply page 3).

This is not found persuasive because the claimed sequences were obtained from different genes and have different primary nucleotide sequences that must be separately searched. A search of more than one distinct nucleotide sequence on the merits in the instant application would place an undue burden on the office.

The traversal is also on the ground(s) that the restriction requirement is inappropriate. Applicants contend that, at least, I-III should be examined simultaneously, because the elected sequence exhibits promoter structure and function whether or not it also comprises other promoter sequences (i.e., a hybrid promoter). Furthermore, Applicants also traverse the

requirement for an election for the hybrid promoter to comprise only one of either a rice actin promoter or a minimal CaMV promoter, as in either case the hybrid promoter also comprises the original disclosed promoter sequence. (reply page 4)

This is not found persuasive because Groups I and II require searches directed to hybrid promoters, in addition to a search of the elected sequence. This is also not found persuasive because a search for a rice actin promoter is a separate search from a search for a minimal CaMV promoter.

With respect to the assertion that I and II-IV and VII-VIII are distinct, Applicants traverse because the structure of a hybrid promoter comprising the disclosed promoter sequence and further comprising another promoter, i.e. CaMV minimal promoter or rice actin promoter, maintains the same double helix molecular structure in situ, as well as promoter function, that said disclosed promoter sequence exhibits alone. Moreover, a search for Claims 14 and 15 (IV), which encompass cells and plants comprising a sequence, would also include a search of the sequence of Claim 1 (III). Accordingly, Applicants maintain that examination of at least I-III and preferably I-IV together would pose no undue burden. (reply pages 4-5)

This is not found persuasive because a search of nucleotide sequences is not based on double helix molecular structure in situ, as all nucleotide sequences maintain the same double helix molecular structure in situ and therefore cannot be distinguished from each other on the basis of this characteristic. This is also not found persuasive because a search of promoter nucleotide sequences is not based on promoter function, as all promoter nucleotide sequences exhibit promoter function and therefore cannot be distinguished from each other on the basis of

this characteristic. This is additionally not found persuasive because while the search of Groups III and IV may be coextensive with respect to a specific nucleotide sequence, Group IV requires an additional search directed to cells and plants, which search is not required for the invention of Group III.

Applicants also traverse the Examiner's claim in the instant Restriction Requirement that: the isolated nucleic acid of Invention I is classified differently from, and differs in structure and function and use from, the cell and transgenic plant of Invention IV, as the claims of Group IV are drawn to the identical sequences, and functions of said sequences, of Group I (reply page 5).

This is not found persuasive because the claims of Group IV (claims 14-15) are not directed to sequences. The claims of Group IV are drawn to a cell comprising a DNA construct (claim 14), and a transgenic plant comprising a DNA construct (claim 15).

Applicants additionally request clarification of the elements of VIII, which references solely Claim 24, as Claims 25-27 are dependent on Claim 24 (reply page 5).

Claims 25-27 were inadvertently left out of the groupings of claims. Claims 25-27 are properly grouped with claim 24 in Group VIII.

Applicants further traverse the Examiner's assertion that the isolated nucleic acid of Invention I is not used in the methods of Inventions VII-VIII, on the grounds that the nucleic acids of I are indeed used in the method of VII as they comprise the identical nucleic acid sequences, and furthermore are indeed produced by the methods of VIII (reply page 5).

This is not found persuasive because the nucleic acids of I are not used in the method of VII. The method of VII uses a DNA construct comprising a promoter comprising (i) a nucleic acid sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, and, operably linked to the promoter, (ii) a transcribable DNA sequence and (iii) a 3' non-translated region, whereas the nucleic acid of I is an isolated nucleic acid comprising a sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, wherein said isolated nucleic acid is a hybrid promoter and wherein said isolated nucleic acid further comprises a minimal CaMV promoter.

This is also not found persuasive because the nucleic acids of I are not produced by the method of VIII. The method of VIII produces 5' flanking and regulatory sequences of unspecified structure from a genomic library prepared from an unspecified target plant using primers specific for an unidentified gene that were designed from EST sequences of unspecified structure remaining after subtraction, whereas the nucleic acid of I is an isolated nucleic acid comprising a sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, wherein said isolated nucleic acid is a hybrid promoter and wherein said isolated nucleic acid further comprises a minimal CaMV promoter.

Applicants also respectfully traverse the examiner's assertion that III and V-VI are related as product and process of use, since the isolated nucleic acid of Invention I can be used in a materially different process of using that product, such as a Southern hybridization method, as the nucleic acid sequence of I is disclosed as being a promoter sequence (reply pages 5-6)

This is not found persuasive because it is well known in the art that any nucleic acid molecule, including a nucleic acid molecule that is a promoter sequence, has the inherent ability to be used in a hybridization method.

Applicants additionally respectfully traverse the Examiner's assertion that Invention II and inventions III-IV and VII-VIII are distinct inventions, as the elements of IV (Claims 14-15), claim a cell or plant comprising the exact nucleic acid sequences disclosed in II; therefore Applicants maintain that said isolated nucleic acid of II is the same as that in IV, and thus does not constitute a separate invention. (reply page 6)

This is not found persuasive because the claims of Group IV (claims 14-15) are not directed to nucleic acids. The claims of Group IV are drawn to a cell and a transgenic plant comprising a DNA construct, classified in class 435, subclass 252.3 and class 800, subclass 298 respectively, whereas the claims of Group II are directed to an isolated nucleic acid, classified in class 536, subclass 24.1. Cells and plants, whether or not they are transgenic, are different compositions from isolated nucleic acids.

Applicants further traverse the Examiner's assertion that Invention II is classified differently from, and not used in or produced by, the methods of inventions VII-VIII, as the nucleic acids of II are indeed used in the method of VII as they comprise the identical nucleic acid sequences, and furthermore are indeed produced by the methods of VIII (reply page 6).

This is not found persuasive because the nucleic acids of II are not used in the method of VII. The method of VII uses a DNA construct comprising a promoter comprising (i) a nucleic

acid sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, and, operably linked to the promoter, (ii) a transcribable DNA sequence and (iii) a 3' non-translated region, whereas the nucleic acid of II is an isolated nucleic acid comprising a sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, wherein said isolated nucleic acid is a hybrid promoter and wherein said isolated nucleic acid further comprises a minimal rice actin promoter.

This is also not found persuasive because the nucleic acids of II are not produced by the method of VIII. The method of VIII produces 5' flanking and regulatory sequences of unspecified structure from a genomic library prepared from an unspecified target plant using primers specific for an unidentified gene that were designed from EST sequences of unspecified structure remaining after subtraction, whereas the nucleic acid of II is an isolated nucleic acid comprising a sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, wherein said isolated nucleic acid is a hybrid promoter and wherein said isolated nucleic acid further comprises a minimal rice actin promoter.

Applicants also respectfully traverse the Examiner's assertion that II and V-VI are related as product and process of use since the isolated nucleic acid of Invention II can be used in a materially different process of using that product, such as a Southern hybridization method, as the nucleic acid sequence of II is disclosed as being a promoter sequence (reply pages 6-7)

This is not found persuasive because it is well known in the art that any nucleic acid molecule, including a nucleic acid molecule that is a promoter sequence, has the inherent ability to be used in a hybridization method.

Applicants additionally respectfully traverse the Examiner's assertion that III and VI and VII-VIII are distinct inventions, as the elements of IV (Claims 14-15), claim a cell or plant comprising the exact nucleic acid sequences disclosed in III; therefore, Applicants maintain that said isolated nucleic acid of III is the same as that in IV, and thus does not constitute a separate invention. (reply page 7)

This is not found persuasive because the claims of Group IV (claims 14-15) are not directed to nucleic acids. The claims of Group IV are drawn to a cell and a transgenic plant comprising a DNA construct, classified in class 435, subclass 252.3 and class 800, subclass 298 respectively, whereas the claims of Group III are directed to an isolated nucleic acid, classified in class 536, subclass 24.1. Cells and plants, whether or not they are transgenic, are different compositions from isolated nucleic acids.

Applicants further traverse the Examiner's assertion that the isolated nucleic acid of Invention III is classified differently from, and is not used in or produced by, the methods of Inventions VII-VIII, as the nucleic acids of III are indeed used in the method of VII as they comprise the identical nucleic acid sequences, and furthermore are indeed produced by the methods of VIII (reply page 7).

This is not found persuasive because the nucleic acids of III are not used in the method of VII. The method of VII uses a DNA construct comprising a promoter comprising (i) a nucleic acid sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, and, operably linked to the promoter, (ii) a transcribable DNA sequence and (iii)

a 3' non-translated region, whereas the nucleic acid of III is an isolated nucleic acid comprising a sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof.

This is also not found persuasive because the nucleic acids of III are not produced by the method of VIII. The method of VIII produces 5' flanking and regulatory sequences of unspecified structure from a genomic library prepared from an unspecified target plant using primers specific for an unidentified gene that were designed from EST sequences of unspecified structure remaining after subtraction, whereas the nucleic acid of III is an isolated nucleic acid comprising a sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof.

Applicants also respectfully traverse the Examiner's assertion that III and V-VI are related as product and process of use since the isolated nucleic acid of Invention III can be used in a materially different process of using that product, such as a Southern hybridization method, as the nucleic acid sequence of II is disclosed as being a promoter sequence (reply page 8).

This is not found persuasive because it is well known in the art that any nucleic acid molecule, including a nucleic acid molecule that is a promoter sequence, has the inherent ability to be used in a hybridization method.

Applicants additionally respectfully traverse the Examiner's assertion that IV and V-VI and VIII are distinct inventions, as the cells and plants disclosed in IV (Claims 14 and 15), and

the methods disclosed in V-VI and VIII (Claims 16-22, 24) are interdependent in that they all comprise the same nucleic acid sequence which has the identical function (reply page 8).

This is not found persuasive because the cell and plant of invention IV are classified differently from, and are not used in or produced by, the methods of inventions V-VI and VIII. The presence of shared common element is not in itself indicative of a lack of distinctness.

Applicants further respectfully traverse the Examiner's assertion that VII and IV are related as process of making and product made since the transgenic plant can be made by another and materially different process, such as by transgenic breeding, as Applicants respectfully maintain that a cell (Claim 14) or a plant (Claim 15) comprising a DNA construct of IV may, by definition, only be produced by a transformation method as described in VIII (Claim 23). In this regard Applicant directs the Examiner to page 10 of the specification. (reply page 9)

This is not found persuasive because the method described in VIII (Claim 23) is not limited to making transgenic plants that cannot reproduce sexually. This is also not found persuasive because page 10 of the specification explicitly states that a transgenic organism also includes progeny produced from a breeding program employing a transgenic plant in a cross, which progeny are not produced by a transformation method as described in VIII.

Applicants also respectfully traverse the Examiner's assertion that V and VI-VIII are distinct inventions, as the methods of V (Claims 16-21) utilize the identical materials as the methods of VI and VII (the same nucleic acid sequences). Moreover, Applicants maintain that

the materials (nucleic acid sequences) utilized in V, VI and VII are produced by the method disclosed in VIII (Claim 24). (reply pages 9-10)

This is not found persuasive because the method of V (Claims 16-21) does not utilize the identical materials as the methods of VI and VII. This is also not found persuasive because the materials utilized in V, VI and VII are not produced by the method disclosed in VIII (Claim 24). VI requires the step of operably linking a minimal promoter to the nucleic acid sequences selected from the group consisting of SEQ ID NOS:79-98 or fragment, region, or cis element thereof, which step and minimal promoter are not required to practice the methods of V and VII. VII requires the step of introducing into a cell of a plant a DNA construct comprising a promoter comprising (i) a nucleic acid sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, and, operably linked to the promoter, (ii) a transcribable DNA sequence and (iii) a 3' non-translated region, which step and DNA construct are not required to practice the methods of V and VI. The method of VIII produces 5' flanking and regulatory sequences of unspecified structure from a genomic library prepared from an unspecified target plant using primers specific for an unidentified gene that were designed from EST sequences of unspecified structure remaining after subtraction, which 5' flanking and regulatory sequences are not utilized in V, VI and VII.

Applicants additionally respectfully traverse the Examiner's assertion that VI and VII-VIII are distinct Inventions, as the methods of VI (Claims 16 and 22) utilize the identical materials as the methods of VII and VIII (the same nucleic acid sequences). Moreover,

Applicants maintain that the materials (nucleic acid sequences) utilized in VI and VII are produced by the method disclosed in VIII (Claim 24). (reply page 10)

This is not found persuasive because the method of VI (Claims 16 and 22) does not utilize the identical materials as the methods of VII and VIII. This is also not found persuasive because the materials utilized in VI and VII are not produced by the method disclosed in VIII (Claim 24). VI requires the step of operably linking a minimal promoter to the nucleic acid sequences selected from the group consisting of SEQ ID N05:79-98 or fragment, region, or cis element thereof, which step and minimal promoter are not required to practice the methods VII and VIII. VII requires the step of introducing into a cell of a plant a DNA construct comprising a promoter comprising (i) a nucleic acid sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, and, operably linked to the promoter, (ii) a transcribable DNA sequence and (iii) a 3' non-translated region, whereas the nucleic acid of II is an isolated nucleic acid comprising a sequence from the group consisting of SEQ ID NOS:79-98 or a fragment, region, or cis element thereof, which step and DNA construct are not required to practice the methods of VI and VIII. The method of VIII produces 5' flanking and regulatory sequences of unspecified structure from a genomic library prepared from an unspecified target plant using primers specific for an unidentified gene that were designed from EST sequences of unspecified structure remaining after subtraction, which 5' flanking and regulatory sequences are not utilized in VI and VII.

Applicants further respectfully traverse the Examiner's assertion that VII and VIII are distinct inventions, as the materials (nucleic acid sequences) utilized in VII are produced by the method disclosed in VIII (Claim 24). (reply page 10)

This is not found persuasive because the method of VIII produces 5' flanking and regulatory sequences of unspecified structure from a genomic library prepared from an unspecified target plant using primers specific for an unidentified gene that were designed from EST sequences of unspecified structure remaining after subtraction, which 5' flanking and regulatory sequences are not utilized in VII.

Claims 3-9 and 14-27, and SEQ ID NOS: 79-89 and 91-98 are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 1 and 10 are objected to because of the following informalities: the claims are directed in part to nonelected sequences. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO:90, does not reasonably provide enablement for other isolated nucleic acids that are fragments, regions or cis elements thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to an isolated nucleic acid comprising a sequence of SEQ ID NO:90, or a fragment, region, or cis element of said sequence thereof, said isolated nucleic acid being capable of regulating transcription of an operably linked DNA sequence, including a promoter sequence that confers expression of operably linked genes in male reproductive tissues.

The specification discloses SEQ ID NO:90 as a promoter sequence isolated from *Zea mays* that exhibits a high level of promoter activity in a wheat reproductive tissue transient assay when operably linked to the hsp70 intron and a GUS reporter gene, and confers anther specific expression of operably linked reporter genes in *Arabidopsis thaliana* and wheat (pages 8, 42, 71, 74, 79 and 81).

The full scope of the claimed invention is not enabled because it is unpredictable what function, if any, would be exhibited by nucleic acids that are fragments, regions or cis elements of SEQ ID NO: 90, because promoter function may be positively or negatively affected by the presence of specific nucleotides and nucleotide sequence motifs in the nucleic acid, which nucleotides and motifs may or may not be present in nucleic acids that are fragments, regions or cis elements of SEQ ID NO: 90.

See, for example, Kim Y. et al. (A 20 nucleotide upstream element is essential for the nopaline synthase (nos) promoter activity. Plant Mol Biol. 1994 Jan;24(1):105-17), who teach that various point mutations in the nos promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

See also, for example, Eyal Y. et al. (Pollen specificity elements reside in 30 bp of the proximal promoters of two pollen-expressed genes. Plant Cell. 1995 Mar;7(3):373-84), who teach that high levels of expression and pollen specificity are maintained in the proximal regions (-115 bp and -100 bp) of the late anther tomato LAT52 and LAT59 genes (page 373 column 2). Eyal et al. also teach that while sequence comparisons of the LAT52 and LAT59 promoters with other pollen-specific gene promoters by McCormick yielded no common conserved regions, conserved sequences (the 56/59 box) at the 5' end of the proximal promoter regions of LAT52 and LAT59 were shared with a single additional pollen-specific gene, LAT56, which conserved sequences were also found to be redundant farther upstream in the LAT52 promoter (page 373 column 2). Eyal et al. additionally teach that functional analysis of LS constructs in transient expression assays in pollen showed that different types of linker substitutions made in the proximal promoter regions of LAT52 and LAT59 increased, decreased, or did not affect, the

level of expression of an operably linked reporter gene (page 374 column 2 first full paragraph; page 375 Figure 1).

In the instant case Applicant has not provided guidance with respect to the identity and location of key nucleotides and regulatory regions that affect the promoter function of SEQ ID NO: 90, and what their specific effects are. Absent such guidance it would require undue experimentation for one skilled in the art to use nucleic acids that are fragments, regions or cis elements of SEQ ID NO: 90, as one skilled in the art would have to test each fragment, region and element for promoter function and/or modify each sequence in order to determine under which conditions, if any, each sequence will function as a promoter in plant cells, or in the male reproductive tissues of a plant. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of "being capable of", as it is unclear whether the claim in fact requires that the isolated nucleic acid regulate transcription.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 and 10-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tacke E. et al. (GenBank Accession No. X88779, Z.mays Glossy2 locus DNA, 09-MAY-1996).

The claims are drawn to an isolated nucleic acid comprising a sequence of SEQ ID NO:90, or a fragment, region, or cis element of said sequence thereof, said isolated nucleic acid being capable of regulating transcription of an operably linked DNA sequence, including a promoter sequence that confers expression of operably linked genes in male reproductive tissues.

Tacke E. et al. teach an isolated nucleic acid comprising a fragment, region, or cis element of SEQ ID NO:90. While Tacke E. et al. are silent with respect to whether their isolated nucleic acid is capable of regulating transcription of an operably linked DNA sequence or conferring expression of operably linked genes in male reproductive tissues, the isolated nucleic acid taught by Tacke E. et al. is presumed to have the functions recited in the rejected claims, as the isolated nucleic acid taught by Tacke E. et al. meets all of the structural limitations recited in the rejected claims, and as the function of an isolated nucleic acid that is a promoter is effected by its structural elements.

Claims 1-2 and 10-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ainley M. et al. (Geneseq Accession Nos. AAV6371 and, AAV63730, 12-APR-1999 from WO9856921-A1, published 17-DEC-1998).

The claims are drawn to an isolated nucleic acid comprising a sequence of SEQ ID NO:90, or a fragment, region, or cis element of said sequence thereof, said isolated nucleic acid being capable of regulating transcription of an operably linked DNA sequence, including a promoter sequence that confers expression of operably linked genes in male reproductive tissues.

Ainley M. et al. teach an isolated nucleic acid comprising a fragment, region, or cis element of SEQ ID NO:90. While Ainley M. et al. are silent with respect to whether their isolated nucleic acid is capable of regulating transcription of an operably linked DNA sequence or conferring expression of operably linked genes in male reproductive tissues, the isolated nucleic acid taught by Ainley M. et al. is presumed to have the functions recited in the rejected claims, as the isolated nucleic acid taught by Ainley M. et al. meets all of the structural limitations recited in the rejected claims, and as the function of an isolated nucleic acid that is a promoter is effected by its structural elements.

See MPEP 2112 III: "Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA1977)."

See also MPEP 2112.01 I: "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)."

Since the Patent Office does not have the facilities to examine and compare the isolated nucleic acid of Applicant with that of Tacke E. et al. or Ainley M. et al., the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

Cynthia Collins
4/20/06